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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/285,429    04/02/99    SHIRLEY    B    5784-9

EXAMINER
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027476    HM12/0921

CHIRON CORPORATION  
INTELLECTUAL PROPERTY - R440  
P.O. BOX 8097  
EMERYVILLE CA 94662-8097

ART UNIT	PAPER NUMBER
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1653

DATE MAILED:

09/21/01

18

**Please find below and/or attached an Office communication concerning this application or proceeding.**

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# Office Action Summary

Application No.  
09/285,429

Applicant(s)  
Shirley

Examiner  
F. MOEZIE

Art Unit  
1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jul 2, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 21-34 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 21-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### **STATUS OF CLAIMS**

Claims 1-14 and the Newly added claims 21-34 are pending prosecution in this Office action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### **NEW GROUND OF REJECTION - 35 U.S.C. 112, FIRST PARAGRAPH**

Claims 1-14 and 21-34 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The terminology "succinate causes less pain on injection" which is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The critical feature(s) that were discovered by applicant are not cited in the claims. See, the response filed by applicant, dated July 2, 2001 at page 5, third paragraph, and page 12, line 28 of the specification.

The earlier rejection of the claims 1-10, 13 and 14 under **35 U.S.C. 112, first paragraph**, regarding the scope of the enablement is maintained for the reasons of record, paper no. 14, page 3, paper no. 14, mailed 12/28/00.

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The rejection of claims 1-10, 13 and 14 under **35 U.S.C. 112, second paragraph**, regarding the indefinite terminology in the claims are maintained for the reasons of record, paper no. 14, page 3. This ground of rejection is extended to encompass the newly added claims 21-34.

In claims 1-14 and 21-34 the term “substantially” render the claims indefinite as to the claims’ metes and bounds. Furthermore, the terms “at least one” and “such that” render the claims indefinite as to the claims’ metes and bounds.

The earlier rejection of claims 1-3 and 6-9 under **35 U.S.C. 102 (b)** as being anticipated by EPA ‘249 is withdrawn in view of the amendments to the claims.

The rejection of claims 11 and 12 under **35 U.S.C. 102 (b)** as being anticipated by Clark et al is withdrawn in view of the amendments.

Claims 1-14 remain rejected under **35 U.S.C. 103 (a)** as being unpatentable over Clark et al and EPA for the reasons of record. This ground of rejection is extended to encompass the newly added claims 21-34.

## **RESPONSE**

Applicant's arguments and amendments filed July 2, 2001 have been fully considered and found persuasive in-part.

The rejection of the claims under **35 U.S.C. 112, first paragraph**, regarding the scope of the enablement is maintained because applicant fails to show a representative number of

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examples for the “pharmaceutically active agents” (organic and inorganic classes of compounds) in the claimed compositions. Reference made to page 8, first paragraph, wherein a myriad of compounds of diverse and distinct (structural and functional) are enumerated is insufficient to overcome this ground of rejection.

The rejection of the claims under **35 U.S.C. 112, second paragraph**, is maintained regarding the indefinite language used in the claims. The term “so that” is indicative of a missing part in a claim. If the object is obtaining isotonicity in the composition, for example, then, the amount effective for said function should be used.

The rejection of the claims under 35 U.S.C. 103 as being unpatentable over Clark et al and EPA is maintained because: a) the claims are not drawn to the invention as described in the specification at page 28, line 12, wherein the succinate “provided an effective medium for subcutaneous injection” and b) the use of succinate in a pharmaceutical composition for the purpose of imparting stability to the composition is taught by the art. Moreover, Acott et al in US 5,985,830 (effective filing date - Sept. 16, 1996) claims that the parenteral use of IGF-I “effective to substantially reduce kidney cyst incidence and/or severity” (claims 10, 21 and 22). Furthermore, succinate is used in the composition (col. 7, line 3). Clearly, reducing the kidney cyst incidence and/or severity is inherently accompanied by reducing pain and said pain reduction could also be inherent in the use of IGF-I, and not succinate. Because there is a clear motivation to use succinate in an injectable solution of a pharmaceutically active composition (IGF-I) and it has been used before as shown above, applicant must show criticality/unobviousness for the use

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of succinate (amounts) in an injectable composition versus the prior art teachings and limit claims thereto.

**CONCLUSION**

No claim is allowed.

Any inquiry concerning this communication should be directed to F.T. Moezie at telephone number (703) 305-4508 or Dr. LOW (SPE) at 308-2923.

*F.T. Moezie*  
F.T. MOEZIE,  
PRIMARY EXAMINER  
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